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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,499	10/11/2000	Roy Curtiss III	3116-1192	5788

21888 7590 04/22/2004

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EXAMINER
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SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/686,499

Applicant(s)

CURTISS, ROY

Examiner

Khatol S Shahnan-Shah

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 24 February 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1-22, 45 and 46.Claim(s) withdrawn from consideration: None.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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***Attachment to Advisory Action***

1. Applicants' Reply to a final office action under 37 CFR 1.116, received 2/24/2004 is acknowledged.
2. Applicants' notice of appeal, received 2/24/2004 is acknowledged.
3. Claims 1-22 and 45-46 are pending in the application.

***Rejections Maintained***

4. Rejection of claims 1, 2, 8- 13, 16 and 21-22 under 35 U.S.C. 102 (e) made in paragraph 9 of the office action mailed on 1/29/2002 (paper number 11) is maintained.

The rejection was as stated below:

Claims 1, 2, 8- 13, 16 and 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Portnoy et al. (US Patent 6,004,815).

Claims are drawn to an attenuated derivative of a pathogenic microorganism, recombinant vector and a gene operably linked to an eukaryotic promoter.

Portnoy et al. disclose an attenuated derivative of a pathogenic microorganism (*E.coli*) (see abstract, table 1 and claims 1-6), plasmid vectors (column 8, table 2) and gene operably linked to an eukaryotic promoter (CMV) (see column 3). They teach *E. coli* deficient in the production of DAP (see column 16) and a recombinant complementing gene on a vector (plasmid pWR 100 from *Shigella flexneri* (column 16). The prior art discloses the claimed products.

Since the office does not have the facilities for examining and comparing applicant's products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art does not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

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Applicant's arguments filed 2/24/2004 have been fully considered but they are not persuasive.

Applicant argues that Portnoy et al. do not teach a vector with a recombinant complementary gene. Applicant argues "The bacteria shown in Table 1 and described in the other parts of Portnoy are merely attenuated and do not possess an non functional native chromosomal essential gene." Applicant further argues that the plasmids in Table 2 in Portnoy et al. do not carry a complementary essential gene.

It is the examiner's position to bring applicant's attention to the fact that Portnoy et al. teach an essential gene that encodes a function that is required for viability as admitted by the applicant in the response. DAP is required for viability of the microorganism. Therefore Portnoy et al. teach an essential gene that encodes a function that is required for viability. In regard to the recombinant complementing gene on an extra chromosomal vector the applicant attention is directed to Table 2. The plasmid pDP3615 carrying strain MC4100 (DE3) an RNA polymerase essential gene. Portnoy also recite in column 3, lines 51-55 "In particular, the polynucleotide may encode a transcription factor, whereby expression of the transcription factor in the target cell provides activation or de-activation of targeted gene expression in the target cell. Thus Portnoy reference teaches each element of the claimed invention.

5. Rejection of claims 1-7, 12-20 and 45-46 under 35 U.S.C. 102 (e) made in paragraph 8 of the office action mailed on 12/16/2002 (paper number 15) is maintained.

The rejection was as stated below:

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Claims 1-7, 12-20 and 45-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Curtiss III et al., (US Patents Number 6024961) Prior art already made of record.

Claims are drawn to an attenuated derivative of a pathogenic microorganism (Enterobacteriaceae) comprising a non functional native essential gene and a recombinant complementing gene on a vector (plasmid) encoding a replacement for an essential enzyme. And the desired gene product is a bacterial antigen. The above product was achieved by the use of the balanced- lethal host-vector system.

Curtiss III et al. (US Patent No. 6024961) disclose an avirulent immunogenic strain of *Salmonella enterica* serotype Typhi having a mutation in one or more genes comprising of pab, pur, aro, asd, dap, nadA, pncB, galE, pmi, fur, rpsL, ompR, htrA, hemA, cdt, cya, crp, phoP, phoQ, rfc, poxA, galU, or a combination thereof. (See claims, figures specially figure 7 and abstract) They also teach a recombinant gene encoding the desired gene product (see column 11). They disclose bacterial antigens (column 11). They also disclose recombinant vectors (example 2, column 28) and desired gene product cytokine (columns 10 and 11). The prior art discloses the claimed products.

Since the office does not have the facilities for examining and comparing applicant's products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art does not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

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Applicant's arguments filed 2/24/2004 have been fully considered but they are not persuasive.

Applicant mainly argues embodiments of US Patent No 5,672,345 as previously done and do not argue the prior art US patent No. 6,024,961 which the anticipation is based upon. Applicant further argues the examples of the instant application. Applicant also argues newer techniques of generating defined deletion mutations.

It is the examiner's position that it appears that the applicant is arguing limitations that are not in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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April 18, 2004

  
RODNEY P. SWARTZ, PH.D  
PRIMARY EXAMINER